



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m2173n
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED LETTER
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-04

October 29, 1998

Mr. Frank J. DiBenedetto, President
Chemline Products, Inc.
12690 34th Street North, Unit C4
Clearwater, FL 33762

Dear Mr. DiBenedetto,

Inspection of your facility on August 28th & 31st, 1998, by FDA Investigator Paul L. Figarole, determined that you manufacture an Anti-Microbial Hand Soap, which product is a human drug within the meaning of section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed several significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs (Title 21, Code of Federal Regulations, Parts 210 and 211), that cause this drug to be adulterated within the meaning of section 501(a)(2)(B) of the Act, as follows:

Failure to have written specifications for finished products or to conduct finished product testing for each batch of drug product.

Failure to have written specifications for acceptance or rejection of each component and to test each component for identity, strength, and quality or receive a report of analysis from each supplier.

Failure to have or maintain Master Production & Control Records or Batch Production & Control Records.

Failure to record on distribution records the lot or control number of drug products.

Mr. Frank J. DiBenedetto

Page 2

October 29, 1998

In addition, the Drug Listing Act of 1972 requires you to register your establishment and list all commercially marketed drug products with the Food and Drug Administration (FDA). While Investigator Figarole was at your firm, he provided Mrs. Michelle D. Helms, Secretary/Treasurer, with Registration and Drug Product Listing Forms and an Instruction Booklet. If you have need of further assistance regarding registration and product listing please call our office at (407) 475-4712 and speak with Sheyla Martinez.

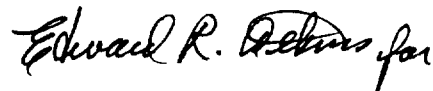
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Please refer to the Form FDA 483, which was left at your firm by the investigator at the close of the inspection. A Copy is included for your information.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite #200, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,

A handwritten signature in cursive script, appearing to read "Douglas D. Tolen".

Douglas D. Tolen
Director, Florida District